Message

From: Giacalone, Robert [/O=CAH/OU=CARDINAL HEALTH/CN=RECIPIENTS/CN=ROBERT.GIACALONE]
Sent: 1/18/2012 2:11:04 PM
To: Morford, Craig [/O=CAH/OU=Cardinal Health/cn=Recipients/cn=craig.morford]; Falk, Steve [/O=CAH/OU=Cardinal Health/cn=Recipients/cn=Steve.Falk]; Bennett, Jeff [/O=CAH/OU=Cardinal Health/cn=Recipients/cn=Jeff.Bennett]
CC: Cacciatore, Gary [/O=CAH/OU=Cardinal Health/cn=Recipients/cn=GCacciat]; Quintero, Gilberto [/O=CAH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Gilberto.quintero]; Mone, Michael [/O=CAH/OU=Cardinal Health/cn=Recipients/cn=Michael.Mone]; 'Moss, Randolph' [Randolph.Moss@wilmerhale.com]; Brian Boynton (brian.boynton@wilmerhale.com) [brian.boynton@wilmerhale.com]; Delia A. Stubbs [DStubbs@hpm.com]; Barber, D. Linden [linden.barber@quarles.com]; Cleveland, Brenda [/O=CAH/OU=Cardinal Health/cn=Recipients/cn=Brenda.Cleveland]; Saxe, Lindsay [Lindsay.Saxe@quarles.com]; Mr. Douglas B. Farquhar (DFarquhar@hpm.com) [DFarquhar@hpm.com]; Goldsand, Corey [/O=CAH/OU=Cardinal Health/cn=Recipients/cn=Corey.Goldsand]
Subject: DEA Guidance Letters, etc.
Attachments: DEA-pharmpak-ltr2-07.tif; DEALtr12-27-07DEALtr-Industry.pdf; Diversion Invest Manual-SuspOrders-2007.pdf; Barber Memo 3-1-07.pdf; DEA-Ltr-9-27-06-Industry.pdf

Per your request, please see the attached DEA guidance letters. In going through my files, I have also included an excerpt from the DEA's Diversion Investigators Manual (-an internal source DI's are suppose to use that I obtained via a FOIA request in 2007). In 2010 I requested a new edition of this Manual but was told that it was unavailable since it was undergoing revisions. I have another request into DEA for the same. In addition, please find attached a memo authored by Linden Barber when he was at the DEA on the topic of suspicious orders. The Barber memo references a 9/27/06 letter to distributors (copy attached) which is essentially the same letter as the 2/7/07 letter (also attached).

Thanks, Bob.

ROBERT P. GIACALONE, RPH, JD | SVP, REGULATORY AFFAIRS & CHIEF REGULATORY COUNSEL | CARDINAL HEALTH
7000 CARDINAL PLACE | DUBLIN, OH 43017 |
TEL: 614.757.7721| FAX: 614.652.4403| EMAIL: ROBERT.GIACALONE@CARDINALHEALTH.COM

PLAINTIFFS TRIAL EXHIBIT
P-08861_00001

U.S. DEPARTMENT OF JUSTICE

DRUG ENFORCEMENT ADMINISTRATION

www.dea.gov

Washington, D.C. 20537

CARDINAL HEALTH
3540 EAST PIKE
ZANESVILLE, OH 43701-0000

February 7, 2007

In reference to registration
RN0209583

Dear Sir or Madam:

This letter is being sent to every commercial entity in the United States registered with the Drug Enforcement Administration (DEA) to distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces.

Background

As each of you is undoubtedly aware, the abuse (nonmedical use) of controlled prescription drugs is a serious and growing health problem in this country.[1] DEA has an obligation to combat this problem as one of the agency's core functions is to prevent the diversion of controlled substances into illicit channels. Congress assigned DEA to carry out this function through enforcement of the Controlled Substances Act (CSA) and DEA regulations that implement the Act.

The CSA was designed by Congress to combat diversion by providing for a closed system of drug distribution, in which all legitimate handlers of controlled substances must obtain a DEA registration and, as a condition of maintaining such registration, must take reasonable steps to ensure that their registration is not being utilized as a source of diversion. Distributors are, of course, one of the key components of the distribution chain. If the closed system is to function properly as Congress envisioned, distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as Congress has expressly declared that the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people.[2]

The Statutory Scheme and Legal Duties of Distributors as DEA Registrants

Although most distributors are already well aware of the following legal principles, they are reiterated here as additional background for this discussion.

The CSA uses the concept of registration as the primary means by which manufacturers, distributors, and practitioners are given legal authority to handle controlled substances. Registration also serves as the primary incentive for compliance with the regulatory requirements of the CSA and DEA regulations, as Congress gave DEA authority under the Act to revoke and suspend registrations for failure to comply with these requirements. (Depending on the circumstances, failure to comply with the regulatory requirements might also provide the basis for criminal or civil action under the CSA.)

[1] See National Institute on Drug Abuse Research Report: Prescription Drug Abuse and Addiction (revised August 2005); available at www.drugabuse.gov/PDF/RRPrescription.pdf

[2] 21 U.S.C. 801(2)

Before taking an action to revoke a registration, DEA must serve the registrant an order to show cause, which advises the registrant of its right to an administrative hearing before the agency (21 U.S.C 824(c)). The CSA also gives DEA discretionary authority to suspend any registration simultaneously with the initiation of revocation proceedings in cases where the agency finds there is an imminent danger to the public health and safety (21 U.S.C. 824(d)).

DEA recognizes that the overwhelming majority of registered distributors act lawfully and take appropriate measures to prevent diversion. Moreover, all registrants - manufacturers, distributors, pharmacies, and practitioners - share responsibility for maintaining appropriate safeguards against diversion. Nonetheless, given the extent of prescription drug abuse in the United States, along with the dangerous and potentially lethal consequences of such abuse, even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm. Accordingly, DEA will use its authority to revoke and suspend registrations in appropriate cases.

The statutory factors DEA must consider in deciding whether to revoke a distributor's registration are set forth in 21 U.S.C. 823(e). Listed first among these factors is the duty of distributors to maintain effective controls against diversion of controlled substances into other than legitimate medical, scientific, and industrial channels. In addition, distributors must comply with applicable state and local law. Congress also gave DEA authority under this provision to revoke a registration based on the distributor's past experience in the distribution of controlled substances and based on "such other factors as may be relevant to and consistent with the public health and safety."

The DEA regulations require all distributors to report suspicious orders of controlled substances. Specifically, the regulations state in 21 C.F.R. 1301.74(b):

> The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

It bears emphasis that the foregoing reporting requirement is in addition to, and not in lieu of, the general requirement under 21 U.S.C. 823(e) that a distributor maintain effective controls against diversion.

Thus, in addition to reporting all suspicious orders, a distributor has a statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels. Failure to exercise such due diligence could, as circumstances warrant, provide a statutory basis for revocation or suspension of a distributor's registration.

In a similar vein, given the requirement under section 823(e) that a distributor maintain effective controls against diversion, a distributor may not simply rely on the fact that the person placing the suspicious order is a DEA registrant and turn a blind eye to the suspicious circumstances. Again, to maintain effective controls against diversion as section 823(e) requires, the distributor should exercise due care in confirming the legitimacy of all orders prior to filling.

In addition, distributors are required to file reports of distributions of certain controlled substances to the DEA ARCOS Unit, in the time and manner specified in the regulations (21 C.F.R. 1304.33). The failure to file ARCOS reports in a complete and timely manner is a potential statutory basis for revocation under section 823(e). Depending on the circumstances, the failure to keep or furnish required records might also be the basis for civil fines or criminal penalties under the CSA, as provided in 21 U.S.C. 842.

Circumstances That Might Be Indicative of Diversion

DEA investigations have revealed that certain pharmacies engaged in dispensing controlled substances for other than a legitimate medical purpose often display one or more of the following characteristics in their pattern of ordering controlled substances:

1. Ordering excessive quantities of a limited variety of controlled substances (e.g., ordering only phentermine, hydrocodone, and alprazolam) while ordering few, if any, other drugs
2. Ordering a limited variety of controlled substances in quantities disproportionate to the quantity of non-controlled medications ordered
3. Ordering excessive quantities of a limited variety of controlled substances in combination with excessive quantities of lifestyle drugs
4. Ordering the same controlled substance from multiple distributors

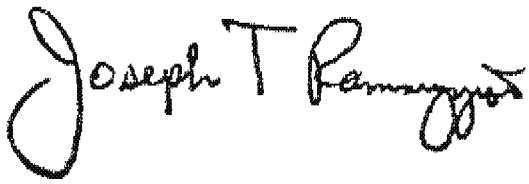
A distributor seeking to determine whether a suspicious order is indicative of diversion of controlled substances to other than legitimate medical channels may wish to inquire with the ordering pharmacy about the following:

1. What percentage of the pharmacy's business does dispensing controlled substances constitute?
2. Is the pharmacy complying with the laws of every state in which it is dispensing controlled substances?
3. Is the pharmacy soliciting buyers of controlled substances via the Internet or is the pharmacy associated with an Internet site that solicits orders for controlled substances?
4. Does the pharmacy, or Internet site affiliated with the pharmacy, offer to facilitate the acquisition of a prescription for a controlled substance from a practitioner with whom the buyer has no pre-existing relationship?
5. Does the pharmacy fill prescriptions issued by practitioners based solely on an on-line questionnaire without a medical examination or bona-fide doctor-patient relationship?
6. Are the prescribing practitioners licensed to practice medicine in the jurisdictions to which the controlled substances are being shipped, if such a license is required by state law?
7. Are one or more practitioners writing a disproportionate share of the prescriptions for controlled substances being filled by the pharmacy?
8. Does the pharmacy offer to sell controlled substances without a prescription?
9. Does the pharmacy charge reasonable prices for controlled substances?
10. Does the pharmacy accept insurance payment for purchases of controlled substances made via the Internet?

These questions are not all-inclusive; nor will the answer to any of these questions necessarily determine whether a suspicious order is indicative of diversion to other than legitimate medical channels. Distributors should consider the totality of the circumstances when evaluating an order for controlled substances, just as DEA will do when determining whether the filling of an order is consistent with the public interest within the meaning of 21 U.S.C. 823(e).

We look forward to continuing to work in cooperation with distributors toward our mutual goal of preventing the diversion of pharmaceutical controlled substances.

Sincerely,



Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control

U.S. DEPARTMENT OF JUSTICE

DRUG ENFORCEMENT ADMINISTRATION

www.dea.gov Washington, D.C. 20537

CARDINAL HEALTH
6012 MOLLOY RD
SYRACUSE NY, 13211-0000

December 27, 2007

In reference to registration
PC0003044

Dear Registrant:

This letter is being sent to every entity in the United States registered with the Drug Enforcement Administration (DEA) to manufacture or distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance manufacturers and distributors to inform DEA of suspicious orders in accordance with 21 CFR 1301.74(b).

In addition to, and not in lieu of, the general requirement under 21 USC 823, that manufacturers and distributors maintain effective controls against diversion, DEA regulations require all manufacturers and distributors to report suspicious orders of controlled substances. Title 21 CFR 1301.74(b), specifically requires that a registrant "design and operate a system to disclose to the registrant suspicious orders of controlled substances." The regulation clearly indicates that it is the sole responsibility of the registrant to design and operate such a system. Accordingly, DEA does not approve or otherwise endorse any specific system for reporting suspicious orders. Past communications with DEA, whether implicit or explicit, that could be construed as approval of a particular system for reporting suspicious orders, should no longer be taken to mean that DEA approves a specific system.

The regulation also requires that the registrant inform the local DEA Division Office of suspicious orders when discovered by the registrant. Filing a monthly report of completed transactions (e.g., "excessive purchase report" or "high unit purchases") does not meet the regulatory requirement to report suspicious orders. Registrants are reminded that their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels. Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted.

The regulation specifically states that suspicious orders include orders of an unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a registrant need not wait for a "normal pattern" to develop over time before determining whether a particular order is suspicious. The size of an order alone, whether or not it deviates from a normal pattern, is enough to trigger the registrant's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the patterns of the registrant's customer base and the patterns throughout the relevant segment of the regulated industry.

Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders. For example, a system that identifies orders as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient. This system fails to identify orders placed by a pharmacy if the pharmacy placed unusually large orders from the beginning of its relationship with the distributor. Also, this system would not identify orders as suspicious if the order were solely for one highly abused controlled substance if the orders never grew substantially. Nevertheless, ordering one highly abused controlled substance and little or nothing else deviates from the normal pattern of what pharmacies generally order.

When reporting an order as suspicious, registrants must be clear in their communications with DEA that the registrant is actually characterizing an order as suspicious. Daily, weekly, or monthly reports submitted by a registrant indicating "excessive purchases" do not comply with the requirement to report suspicious orders, even if the registrant calls such reports "suspicious order reports."

Lastly, registrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion. Failure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 USC 823 and 824, and may result in the revocation of the registrant's DEA Certificate of Registration.

For additional information regarding your obligation to report suspicious orders pursuant to 21 CFR 1301.74(b), I refer you to the recent final order issued by the Deputy Administrator, DEA, in the matter of Southwood Pharmaceuticals Inc., 72 FR 36487 (2007). In addition to discussing the obligation to report suspicious orders when discovered by the registrant, and some criteria to use when determining whether an order is suspicious, the final order also specifically discusses your obligation to maintain effective controls against the diversion of controlled substances.

Sincerely,

Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control

U.S. Department of Justice

Drug Enforcement Administration

Washington, D.C. 20537

Request Number: 03-1134-F

Subject of Request: DIVERSION INVESTIGATORS MANUAL

CARDINAL HEALTH
7000 CARDINAL PLACE
DUBLIN, OH 43017

DEAR ROBERT P. GIACALONE:

Your Freedom of Information/Privacy Act (FOI/PA) request seeking information from the Drug Enforcement Administration (DEA) has been processed. The paragraphs checked below apply:

[ ] A determination has been made to deny your request pursuant to subsections of the Privacy Act and/or Freedom of Information Act referenced at the end of this letter. The exemption number(s) indicated by a mark appearing in the block to the left of the subsection cited constitutes the authority for withholding the deleted material. An attachment to this letter explains these exemptions in more detail.

[X] The processing of your request identified certain materials that will be released to you. Portions not released are being withheld pursuant to the Freedom of Information Act, 5 U.S.C. 552, and/or the Privacy Act, 5 U.S.C. 552a. Please refer to the list enclosed with this letter that identifies the authority for withholding the deleted material, which is indicated by a mark appearing in the block next to the exemption. An additional enclosure with this letter explains these exemptions in more detail.

[X] The documents are being forwarded to you with this letter.

[ ] The rules and regulations of the Drug Enforcement Administration applicable to Freedom of Information Act requests are contained in the Code of Federal Regulations, Title 28, Part 16, as amended. They are published in the Federal Register and are available for inspection by members of the public.

[ ] Certain DEA documents contained information furnished by another government agency. DEA is in the process of consulting with that agency before granting access to the documents in accordance with 28 C.F.R 16.4 and/or 16.42. You will be notified if more material is available for release pending results from that consultation.

[ ] Certain DEA files contain information that was furnished by another government agency or agencies. That information and a copy of your request have been referred for a decision as to access and the agency or agencies involved will respond directly to you in accordance with 28 C.F.R 16.4 and/or 16.42.

[ ] If you wish to appeal any denial of your request, you may do so within sixty (60) days pursuant to 28 C.F.R. 16.9. The appeal should be sent to the following address, with the envelope marked "FOIA Appeal":

Co-Director
Office of Information and Privacy
FLAG Building, Suite 570
Washington, D.C. 20530

[ ] For further information, see attached comments page.

Sincerely,

Katherine Myrick

Katherine L. Myrick
Chief, Operations Unit
FOI/Records Management Section
Drug Enforcement Administration
Washington, D.C. 20537

Number of Pages Withheld: 000

Number of Pages Released: 226

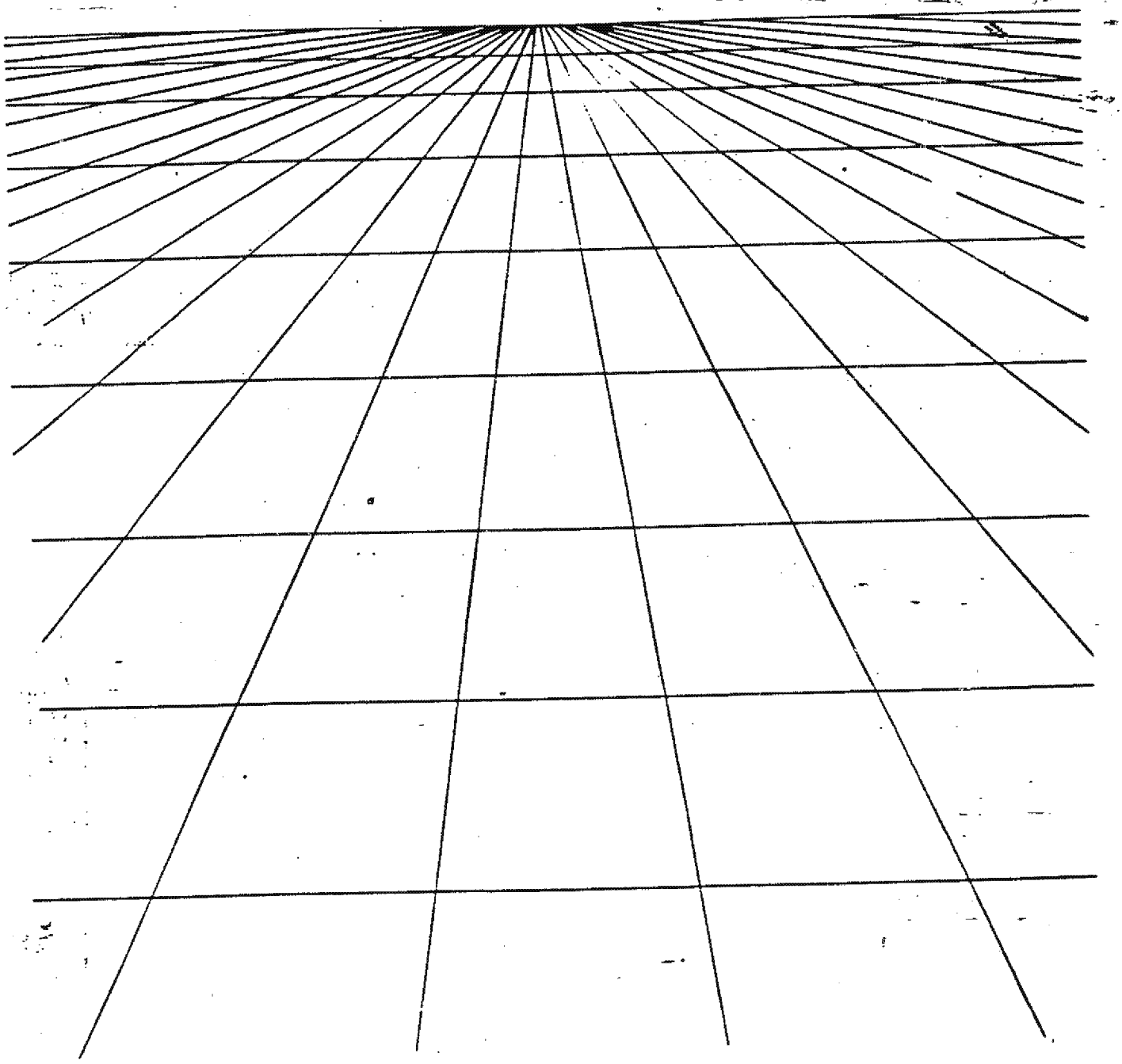
Number of Pages Referred to another agency: 000

APPLICABLE SECTIONS OF THE FREEDOM OF INFORMATION AND/OR PRIVACY ACT:

Freedom of Information Act 5 U.S.C. 552			Privacy Act 5 U.S.C. 552a	
[ ] (b)(1)	[ ] (b)(5)	[ ] (b)(7)(C)	[ ] (d)(5)	[ ] (k)(2)
[X] (b)(2)	[ ] (b)(6)	[ ] (b)(7)(D)	[ ] (j)(2)	[ ] (k)(5)
[ ] (b)(3)	[ ] (b)(7)(A)	[X] (b)(7)(E)	[ ] (k)(1)	[ ] (k)(6)
[ ] (b)(4)	[ ] (b)(7)(B)	[ ] (b)(7)(F)		

U.S. Department of Justice
Drug Enforcement Administration

Diversion Investigators Manual



The FBI is responsible for actions under this Section. If DEA receives information (e.g., telephonic, DEA-106) of a registrant theft which appears to meet the above criteria, DEA shall immediately notify the FBI office having jurisdiction. Additionally, the registrant will be reminded to immediately contact and inform the local police agency of the theft. DO NOT send a copy of all DEA-106's to the FBI, only those which appear to meet one or more of the above criteria.

If the theft meets one of the criteria listed above, DEA will provide to the FBI, on request, case files regarding security at the firm, which may include past thefts or information on suspected violations.

5125 COMPLIMENTARY SAMPLES

It is the policy of DEA to encourage drug manufacturers not to distribute controlled substance samples through detailmen, but to substitute other, safer methods of promoting their products. These methods could include sending samples to physicians directly and not through detailmen, and to institute complimentary prescriptions.

Order forms are required for samples of such substances listed in Schedule II.

The written requests will be preserved by the registrant with his or her distribution records. The request will contain the name, address and registration number of the customer and the name and quantity of the controlled substances.

5126 REQUIREMENT TO REPORT SUSPICIOUS ORDERS

Registrants are required to inform DEA of suspicious orders in accordance with 21 CFR 1301.74(b). DEA field offices are not to approve or disapprove supplier shipments of controlled substances. The responsibility for making the decision to ship rests with the supplier. An exception to this occurs when a supplier complies with a DEA field office's request to initiate a controlled delivery of controlled substances.

DEA field offices will provide the supplier with the related registration information (i.e., whether the customer is currently registered with DEA) needed to assist the supplier in making an independent decision on whether to ship controlled substances.

Registrants, who routinely report suspicious orders, yet fill these orders, with reason to believe they are destined for the illicit market, are expressing an attitude of irresponsibility

that is a detriment to the public health and safety as set forth in 21 U.S.C. 823 and 824. Suspicious orders include those which are in excess of legitimate medical use or exhibit characteristics leading to possible diversion such as: orders of unusual size, unusual frequency, or those deviating substantially from a normal pattern. The supplier can determine whether the order is excessive by checking their own sales and establishing the average amount of controlled substances shipped to registrants of the same apparent size in a particular geographic area. If the customer exceeds this threshold, the request should be viewed as suspicious. This activity, over extended periods of time, would lead a reasonable person to believe that controlled substances possibly are being diverted. An investigation will be conducted for possible violation of the CSA and regulations upon determining that the reporting registrant, as a general practice, does not voluntarily halt shipments of controlled substances to registrants involved in suspected diversion or to registrants against whom previous action has been taken. In these instances, the registrant is subject to the appropriate prosecution and/or administrative action.

Memorandum

Subject	Date
Legal Guidance on Reporting Suspicious Orders Pursuant to 21 C.F.R. § 1301.74(b)	March 1, 2007

To

Diversion Program Mangers

From

D. Linden Barber
Associate Chief Counsel
Diversion and Regulatory Litigation Section

Investigations of wholesale distributors have revealed many distributors are not filing suspicious order reports. Some Diversion Investigators may not be requiring strict compliance with 21 C.F.R. § 1301.74(b). A registrant's compliance with 21 C.F.R. § 1301.74(b) can be a useful tool for investigators to initiate investigations against registrants. Likewise, a registrant's failure to report suspicious orders provides a strong basis for revoking a registration. In light of the importance of this requirement, I ask you to remind all Diversion Investigators to strictly enforce the requirement to file suspicious order reports that comport with the regulation, as discussed below. This is especially important as DEA enters Phase II of Operation Lightning Strike, an initiative focusing on the wholesale distributors that supply controlled substances to pharmacies filling orders for rogue Internet websites.

The regulation specifically requires that a registrant design and operate a system to disclose suspicious orders of controlled substances. While it is appropriate for a Diversion Investigator to provide guidance to registrants with respect to their suspicious order reporting system, it remains the sole responsibility of the registrant to design and operate such a system. As such, Diversion Investigators should not approve or otherwise endorse any specific system for reporting suspicious orders. Doing so may undermine a case against a registrant wherein DEA alleges that the registrant failed to disclose suspicious orders as required by the regulation.

Diversion Investigators should remind registrants that the regulation defines suspicious orders as orders of an unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency. These criteria are disjunctive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a registrant need not wait for a "normal pattern" to develop over time before determining whether a particular order is suspicious. The size of an order alone, whether or not it deviates from a normal pattern, is enough to trigger the registrant's responsibility to report the order as suspicious. Registrants should be further counseled that the determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the patterns of the registrant's customer base and the patterns throughout the relevant segment of the regulated industry.

Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders. For example, a system that identifies orders as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the previous month by 5% or more is insufficient. This system fails to identify orders placed by a pharmacy if the pharmacy placed unusually large orders from the beginning of its relationship with the distributor. Also, this system would not identify orders as suspicious if the order were solely for one highly abused controlled substance if the orders never grew by more than 5%. Nevertheless, ordering one highly abused controlled substance and nothing else deviates from the normal pattern of what pharmacies generally order.

The regulation requires that the registrant inform the Field Division Office of suspicious orders when discovered by the registrant. It appears that many within the regulated industry file a monthly report on "excessive purchases." This does not meet the regulatory requirement for a suspicious order report. When reporting an order as suspicious, registrants must be clear in their communications with DEA, and the Diversion Investigator must ensure, that the registrant is actually characterizing an order as suspicious. Daily, weekly, or monthly reports submitted by a registrant indicating "excessive purchases" are not suspicious order reports. These reports may help the distributor and DEA identify suspicious customers. However, suspicious orders must be reported when discovered by the registrant. An order that is suspicious on its face must be reported when the registrant receives the order, not at the end of the month.

Registrants who have been allowed to file monthly "excessive purchase" reports may complain that reporting suspicious orders when the registrant receives the order is too burdensome. We must emphasize that the requirement to report suspicious orders when discovered is only one aspect of the registrant's duties. In a letter dated September 27, 2006, sent to all distributors, Mr. Rannazzisi stated: "Thus, in addition to reporting all suspicious orders, a distributor has a statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels. Failure to exercise such due diligence could, as circumstances warrant, provide a statutory basis for revocation or suspension of a distributor's registration." It is appropriate, and strongly recommended, that Diversion Investigators ask registrants who file suspicious order reports what steps the registrant took prior to filling the order to ensure that the recipient was not diverting the controlled substances. Registrants should be advised that failing to timely file suspicious order reports, or routinely reporting suspicious orders, yet filling those orders with reason to believe that the controlled substances are being diverted, demonstrates a failure to maintain effective controls against diversion and may result in the revocation or suspension of the registrant's DEA Certificate of Registration.

It is imperative that DEA speak with one voice on this issue. The failure of reputable distributors to report suspicious orders in the manner required in the regulation, and the filling of orders that distributors know, or should know, are likely to be diverted, has greatly contributed to the diversion and abuse of pharmaceutical controlled substances, a problem that is now greater than the abuse of cocaine, heroin, and methamphetamine. We must demand that registrants fulfill the obligations placed upon them when they voluntarily became a participant in a highly regulated industry.

Please contact me at 202-307-5434 if you have questions regarding this memorandum.

U.S. DEPARTMENT OF JUSTICE

DRUG ENFORCEMENT ADMINISTRATION

www.dea.gov

Washington, D.C. 20537
September 27, 2006

Dear Sir or Madam:

This letter is being sent to every commercial entity in the United States registered with the Drug Enforcement Administration (DEA) to distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces.

Background

As each of you is undoubtedly aware, the abuse (nonmedical use) of controlled prescription drugs is a serious and growing health problem in this country.[1] DEA has an obligation to combat this problem as one of the agency's core functions is to prevent the diversion of controlled substances into illicit channels. Congress assigned DEA to carry out this function through enforcement of the Controlled Substances Act (CSA) and DEA regulations that implement the Act.

The CSA was designed by Congress to combat diversion by providing for a closed system of drug distribution, in which all legitimate handlers of controlled substances must obtain a DEA registration and, as a condition of maintaining such registration, must take reasonable steps to ensure that their registration is not being utilized as a source of diversion. Distributors are, of course, one of the key components of the distribution chain. If the closed system is to function properly as Congress envisioned, distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as Congress has expressly declared that the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people.[2]

The Statutory Scheme and Legal Duties of Distributors as DEA Registrants

Although most distributors are already well aware of the following legal principles, they are reiterated here as additional background for this discussion.

The CSA uses the concept of registration as the primary means by which manufacturers, distributors, and practitioners are given legal authority to handle controlled substances. Registration also serves as the primary incentive for compliance with the regulatory requirements of the CSA and DEA regulations, as Congress gave DEA authority under the Act to revoke and suspend registrations for failure to comply with these requirements. (Depending on the circumstances, failure to comply with the regulatory requirements might also provide the basis for criminal or civil action under the CSA.)

[1] See National Institute on Drug Abuse Research Report: Prescription Drug Abuse and Addiction (revised August 2005); available at www.drugabuse.gov/PDF/RRPrescription.pdf

[2] 21 U.S.C. 801(2)

STM-02/27/07

3-8

Before taking an action to revoke a registration, DEA must serve the registrant an order to show cause, which advises the registrant of its right to an administrative hearing before the agency (21 U.S.C. 824(c)). The CSA also gives DEA discretionary authority to suspend any registration simultaneously with the initiation of revocation proceedings in cases where the agency finds there is an imminent danger to the public health and safety (21 U.S.C. 824(d)).

DEA recognizes that the overwhelming majority of registered distributors act lawfully and take appropriate measures to prevent diversion. Moreover, all registrants - manufacturers, distributors, pharmacies, and practitioners - share responsibility for maintaining appropriate safeguards against diversion. Nonetheless, given the extent of prescription drug abuse in the United States, along with the dangerous and potentially lethal consequences of such abuse, even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm. Accordingly, DEA will use its authority to revoke and suspend registrations in appropriate cases.

The statutory factors DEA must consider in deciding whether to revoke a distributor's registration are set forth in 21 U.S.C. 823(e). Listed first among these factors is the duty of distributors to maintain effective controls against diversion of controlled substances into other than legitimate medical, scientific, and industrial channels. In addition, distributors must comply with applicable state and local law. Congress also gave DEA authority under this provision to revoke a registration based on the distributor's past experience in the distribution of controlled substances and based on "such other factors as may be relevant to and consistent with the public health and safety."

The DEA regulations require all distributors to report suspicious orders of controlled substances. Specifically, the regulations state in 21 C.F.R. 1301.74(b):

> The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

It bears emphasis that the foregoing reporting requirement is in addition to, and not in lieu of, the general requirement under 21 U.S.C. 823(e) that a distributor maintain effective controls against diversion.

Thus, in addition to reporting all suspicious orders, a distributor has a statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels. Failure to exercise such due diligence could, as circumstances warrant, provide a statutory basis for revocation or suspension of a distributor's registration.

In a similar vein, given the requirement under section 823(e) that a distributor maintain effective controls against diversion, a distributor may not simply rely on the fact that the person placing the suspicious order is a DEA registrant and turn a blind eye to the suspicious circumstances. Again, to maintain effective controls against diversion as section 823(e) requires, the distributor should exercise due care in confirming the legitimacy of all orders prior to filling.

In addition, distributors are required to file reports of distributions of certain controlled substances to the DEA ARCOS Unit, in the time and manner specified in the regulations (21 C.F.R. 1304.33). The failure to file ARCOS reports in a complete and timely manner is a potential statutory basis for revocation under section 823(e). Depending on the circumstances, the failure to keep or furnish required records might also be the basis for civil fines or criminal penalties under the CSA, as provided in 21 U.S.C. 842.

STM-02/27/07

Circumstances That Might Be Indicative of Diversion

DEA investigations have revealed that certain pharmacies engaged in dispensing controlled substances for other than a legitimate medical purpose often display one or more of the following characteristics in their pattern of ordering controlled substances:

1. Ordering excessive quantities of a limited variety of controlled substances (e.g., ordering only phentermine, hydrocodone, and alprazolam) while ordering few, if any, other drugs
2. Ordering a limited variety of controlled substances in quantities disproportionate to the quantity of non-controlled medications ordered
3. Ordering excessive quantities of a limited variety of controlled substances in combination with excessive quantities of lifestyle drugs
4. Ordering the same controlled substance from multiple distributors

A distributor seeking to determine whether a suspicious order is indicative of diversion of controlled substances to other than legitimate medical channels may wish to inquire with the ordering pharmacy about the following:

1. What percentage of the pharmacy's business does dispensing controlled substances constitute?
2. Is the pharmacy complying with the laws of every state in which it is dispensing controlled substances?
3. Is the pharmacy soliciting buyers of controlled substances via the Internet or is the pharmacy associated with an Internet site that solicits orders for controlled substances?
4. Does the pharmacy, or Internet site affiliated with the pharmacy, offer to facilitate the acquisition of a prescription for a controlled substance from a practitioner with whom the buyer has no pre-existing relationship?
5. Does the pharmacy fill prescriptions issued by practitioners based solely on an on-line questionnaire without a medical examination or bona-fide doctor-patient relationship?
6. Are the prescribing practitioners licensed to practice medicine in the jurisdictions to which the controlled substances are being shipped, if such a license is required by state law?
7. Are one or more practitioners writing a disproportionate share of the prescriptions for controlled substances being filled by the pharmacy?
8. Does the pharmacy offer to sell controlled substances without a prescription?
9. Does the pharmacy charge reasonable prices for controlled substances?
10. Does the pharmacy accept insurance payment for purchases of controlled substances made via the Internet?

These questions are not all-inclusive; nor will the answer to any of these questions necessarily determine whether a suspicious order is indicative of diversion to other than legitimate medical channels. Distributors should consider the totality of the circumstances when evaluating an order for controlled substances, just as DEA will do when determining whether the filling of an order is consistent with the public interest within the meaning of 21 U.S.C. 823(e).

We look forward to continuing to work in cooperation with distributors toward our mutual goal of preventing the diversion of pharmaceutical controlled substances.

Sincerely,

Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control

STM-02/27/07